DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

DOCKETS TRANSMITTAL MEMO

Date: NOV 19 2003

From: Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Fitovit (An Herbal Dietary Supplement)

Firm: EGN Pharma, Inc.

Date Received by FDA: 2/21/03

90-Day Date: 5/22/03

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Tanya Jackson

Tanya Jackson, Interdisciplinary Scientist, HFD 810

95S-0316

RPT174

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

MAY 12 2003

Shanta Chawla, M.D.
Director, Medical and Regulatory Affairs
EGN Pharma, Inc.
7 Fayence
Newport Beach, California 92657

Dear Dr. Chawla:

This is in response to your new dietary ingredient premarket notification dated February 14, 2003, that you submitted pursuant to 21 U.S.C. 350b(a)(2) and Title 21 of the Code of Federal Regulations (21 CFR) Part 190.6 and received by the Food and Drug Administration (FDA) on February 21, 2003. Your notification concerns the powdered herbal mixture which you plan to market under the trade name "Fitovit ™" which you assert contains new dietary ingredients. You indicated that the herbal ingredients are dried to powders and packaged in a capsule. The suggested condition of use is as a dietary supplement; the recommended dosage is one capsule per day. However, you have not specifically identified the name of the new dietary ingredient(s) that is/are the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical. Therefore, this notification does not comply with 21 CFR 190.6 and is incomplete.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA is unable to determine whether the scientific studies you cite provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information you have provided is incomplete. If you market your product without submitting an amended notification that meets the requirements of 21 CFR 190.6, or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

In addition, in any resubmission we would encourage you to clearly describe how the characteristics of any test materials submitted in support of safety are quantitatively and qualitative related to the dietary supplement to be marketed.

Your notification will be kept confidential for 90 days after the filing date of February 21, 2003. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-1775.

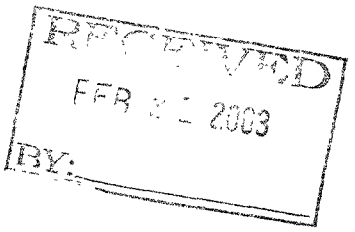
Sincerely yours,

MD
FOR

Susan J. Walker, M.D.
Acting Division Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

EGN Pharma, Inc.
7 Fayence
Newport Beach, CA 92657

February 14, 2003



Ms. Felicia B. Satchell
Office of Nutritional Products, Labeling and Dietary Supplements
FDA, Center for Food Safety and Applied Nutrition
5100 Point Branch Parkway
College Park, MD 20740

RE: New Dietary Ingredient Notification-Fitovit

Dear Ms. Satchell:

This submission is being made in compliance with 21 CFR section 190.6 of Food, Drug, and Cosmetic Act. An original and two copies of notification are being submitted for your review.

We plan to market Fitovit as "An herbal dietary supplement," in two formulations: Fitovit M (for men) and Fitovit F (for women). Both formulations contain identical ingredients, with the exception of one. Also, there are minor differences in the quantities of certain ingredients in the two formulations. These ingredients have been used in Ayurvedic medicine for over one hundred years without any reported untoward effects.

Pursuant to 21 CFR section 101.36, the labels for both formulations are enclosed.

If you have any questions, please do not hesitate to contact us.

Thank you,

Sincerely,

Shanta Chawla M.D.
Director, Medical and Regulatory Affairs
EGN Pharma, Inc.
7 Fayence
Newport Beach, CA 92657
Cell: (949) 413-3704
Work: (949) 743-9257
Email: schawla@cox.net